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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,293

08/14/2006

Debbie Stevens-Wright

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EXAMINER

LEE, BENJAMIN HYOUNGSOL

ART UNIT

PAPER NUMBER

4137

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DELIVERY MODE

07/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,293	Applicant(s) STEVENS-WRIGHT ET AL.	
	Examiner BENJAMIN LEE	Art Unit 4137	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/14/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 15, 20-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-13, 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/14/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of **Species I** (claims 1-7, 11-13, 16-19) in the reply filed on 6/17/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

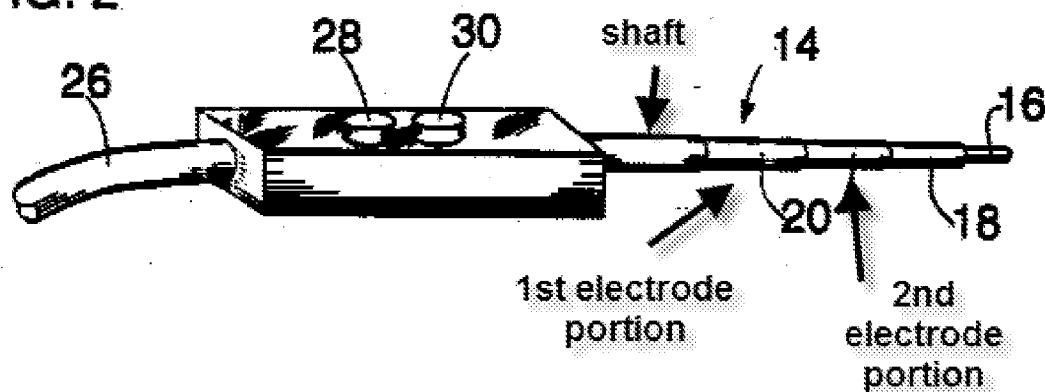
3. **Claims 1-2, 4, 6-7, and 16-18** are rejected under 35 U.S.C. 102(b) as being anticipated by Goldhaber (U.S. Patent No. 5,234,429).

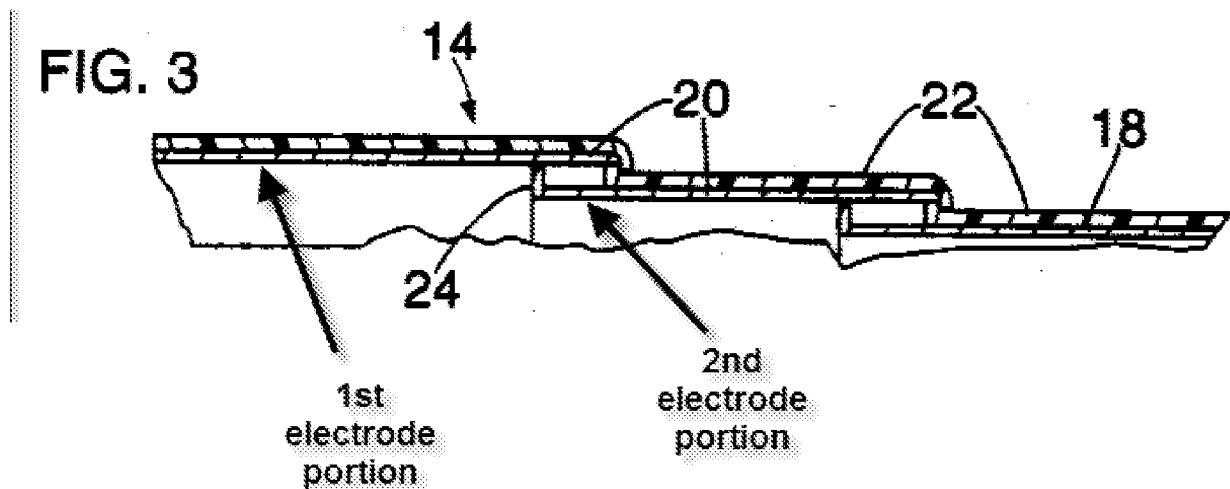
As to claim 1, Goldhaber discloses a catheter (a tubular medical device for insertion into body cavities, according to Merriam-Webster Dictionary) comprising a longitudinal catheter shaft as labeled in Fig. 2 below. The device is for positioning an ablation electrode 14 within a patient's body since the device has a waveform for cutting (col. 1, lines 14-19). The ablation electrode has an outer surface that is as a whole disposed **on** a shaft since its most proximal portion (labeled 1st electrode portion below) rests inside the shaft and sits **on** the inner surface of the shaft (Fig. 2, col. 3, lines 9-12). Furthermore, each tube of ablation electrode 14 has an electrode portion since they are

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electrically connected to the operative tip (Fig. 3, lines 9-22). The limitations of claim 1 do not preclude the possibility of an insulation layer over the electrode as seen in Fig. 3. The electrode is convertible from a first configuration in which the electrode outer surface has a first axial size and a first radial size (Fig. 1) to a second configuration in which the electrode outer surface has a second axial size and maintains the first radial size (Fig. 2, col. 3, lines 32-37).

As to claim 2, Goldhaber teaches that the ablation electrode comprises a first electrode portion and a second electrode portion (see Figs. 2-3 below). Again, the limitations of claim 2 do not preclude the possibility of an insulation layer over the electrode portions as seen in Fig. 3. The second electrode portion has a length and is moveable in the axial direction of the catheter (Figs. 1 & 2, col. 3, lines 32-37). In the first configuration, more of the second electrode portion length is contained within the first electrode portion than in the second configuration as inferred from Figs 1 & 2.

FIG. 2



As to claim 4, Goldhaber teaches that the ablation electrode comprises a third electrode portion (18) that is at least partially contained within the second electrode portion in the first configuration, as shown in Fig. 1.

As to claim 6, Goldhaber teaches that the ablation electrode is a ring electrode since the electrode has a ring shape as shown in Figs. 1 & 2.

As to claim 7, Goldhaber teaches that the first electrode portion and the second electrode portion are cylindrical since they are tubular (Figs. 2 & 3, col. 3, lines 9-12).

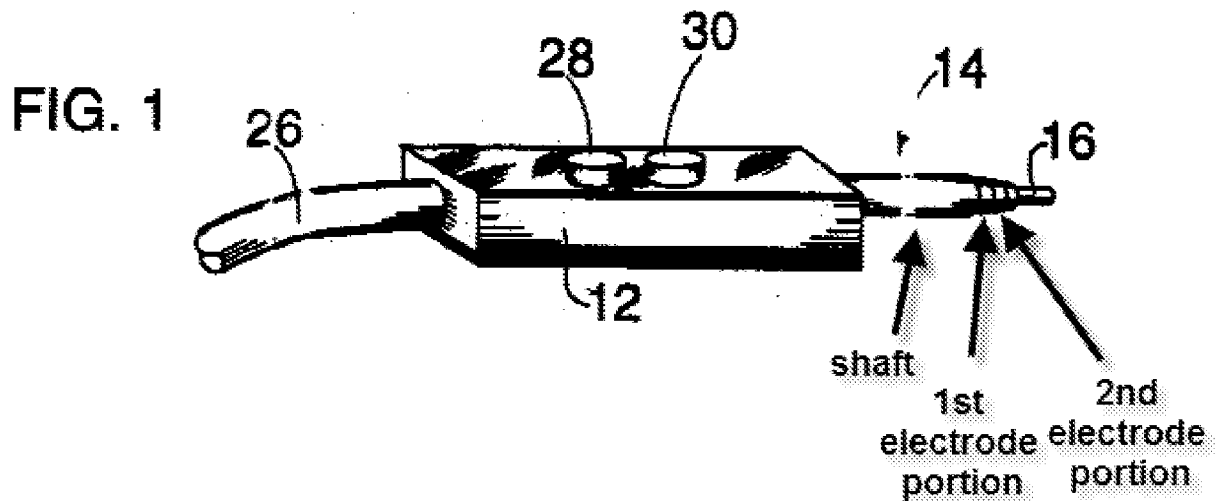
As to claim 16, Goldhaber teaches an ablation electrode 14 for ablating tissue (col. 1, lines 14-19) comprising a first ablation electrode portion configured for mounting on a catheter shaft (see Fig 2 above). The first electrode portion is called a first ablation electrode portion since it is electrically connected to the ablating operative tip 16. The first ablation electrode portion has an outer surface (16) configured to emit electrical energy since it is electrically connected to the supply line carrying the appropriate

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waveform (col. 3, lines 19-23). A second ablation electrode portion is configured for mounting on the catheter shaft (see Fig. 2 above) and has a surface configured to emit electrical energy since it is electrically connected to the supply line carrying the appropriate waveform (col. 3, lines 19-23). The second ablation electrode portion is moveable from a first position substantially inside the first ablation electrode portion to a second position substantially outside the first ablation electrode portion as shown in Figs 1 & 2 (col. 3, lines 32-37).

As to claim 17, Goldhaber teaches the ablation electrode has a third ablation electrode portion (18) configured for mounting on the catheter shaft (Fig. 1), the third ablation electrode portion having a surface configured to emit electrical energy since it is electrically connected to the supply line carrying the appropriate waveform (col. 3, lines 19-23). The third ablation electrode portion is moveable from a first position substantially inside the second ablation electrode portion to a second position substantially outside the second ablation electrode portion as shown in Figs 1 & 2 (col. 3, lines 32-37).

As to claim 18, Goldhaber teaches a longitudinal catheter shaft as explained in regards to claim 16 above. The device, including the longitudinal catheter shaft, is for positioning an ablation electrode within a patient's body (col. 3, lines 32-41). The first ablation electrode and the second ablation electrode are mounted on the catheter shaft as seen in Fig. 1 below.



4. **Claims 1-3, 5-7 and 11** are rejected under 35 U.S.C. 102(b) as being anticipated by Silvestrini (WO 95/20360).

As to claim 1, Silvestrini teaches a catheter (pg. 1, ¶ 4). comprising a longitudinal catheter shaft 5 for positioning an ablation electrode 2 within a patients body (pg. 1, ¶ 4). A portion of an ablation electrode 2 is disposed on the shaft 5 and has an outer surface (Fig. 3). The electrode is convertible form a first configuration in which the electrode outer surface has a first axial size and a first radial size to a second configuration where the electrode outer surface has a second axial size and maintains the first radial size since the electrode are telescopically slidable relative to one another (pg. 8, ¶ 3).

As to claim 2, Silvestrini teaches the ablation electrode has a first electrode portion 2 and a second electrode portion 4 (Fig. 3). Note that the second electrode portion is on an inner surface of shaft 5. The second electrode portion has a length and is moveable

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in the axial direction of the catheter (Fig. 3, pg. 8, ¶ 3). In the first configuration more of the second electrode portion length is contained within the first electrode portion than in the second configuration since the electrode portions are telescopically slidable relative to one another (pg. 8, ¶ 3) and can be visualized by comparing Figs. 1 and 3.

As to claim 3, Silvestrini teaches the second electrode portion length is fully contained within the second electrode portion in the first configuration (Fig. 1, page 9, ¶ 2).

As to claim 5, Silvestrini teaches a wire that is connected to the second electrode portion (pg. 7, ¶ 2) and is capable of being pulled or pulling the second electrode portion since it steers the second electrode portion.

As to claim 6, Silvestrini teaches that the ablation electrode is a ring electrode (pg. 3, ¶ 2, Fig. 3).

As to claim 7, Silvestrini teaches that the first electrode portion and second electrode portion are cylindrical (pg. 3, ¶ 2, pg. 4, ¶ 1, Fig. 3).

As to claim 11, Silvestrini teaches a catheter with a longitudinal catheter shaft 5 (Fig. 3) for positioning an ablation electrode within a patient's body (pg. 1, ¶ 1).

Silvestrini teaches an ablation electrode 2 is disposed on the shaft 5, and the electrode 2 has a continuous outer ablating surface area since the electrode's surface area is connected to an RF generator (pg. 8, ¶ 2). The outer ablating surface area is adjustable since the electrode portions are telescopically slidable relative to one another (pg. 8, ¶ 3), thus exposing or hiding surface area of the ablation electrode. Silvestrini teaches the

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electrode is substantially comprised of metal since it is fabricated from conventional metallic electrode material (pg. 3, ¶ 3).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldhaber (U.S. Patent No. 5,234,429), as applied to claim 2 above, in view of Silvestrini (WO 95/20360).

As to claim 3, it is unclear whether Goldhaber teaches that in the first configuration, the second electrode portion length is fully contained within the first electrode portion. Silvestrini teaches a telescoping bipolar electrode device where the second electrode portion length is fully contained within the first electrode portion in order to advance the electrode through a lumen of a vessel of the human body (page 9, ¶ 2). It would have been obvious to one of ordinary skill in the art at the time of the invention to have the second electrode portion length fully contained within the first electrode portion in order to advance the electrode through a lumen of a vessel of the human body (page 9, ¶ 2) without risking inadvertently penetrating a sidewall.

7. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldhaber (U.S. Patent No. 5,234,429), as applied to claim 2 above, in view of Watson (U.S. Patent No. 5,788,715).

As to claim 5, Goldhaber teaches that the instrument is pulled out from the retract configuration to the extended configuration, but does not specifically disclose the actuation mechanism employed. Goldhaber does not expressly teach that a pull wire is connected to the second electrode portion. However, Watson teaches that successive cylinders are arranged so that they telescope sequentially with successive applications of pulling forces on a pull wire (col. 4, lines 42-50). The pull wires 454b-c and trip wire are directly connected to telescoping cylinders (Fig. 13) in order to actuate the telescoping movement (col. 16, lines 44-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement a wire, such as the pull wire or trip wire of Watson, connected to the second electrode portion because Watson teaches that successive cylinders are arranged so that they telescope sequentially with successive applications of pulling forces on a pull wire (col. 4, lines 42-50), and the connection the second electrode portion would give the user the ability to control the extension/retraction of the second electrode.

8. **Claims 11-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldhaber (U.S. Patent No. 5,234,429), in view of Eggers (U.S. Patent 5,810,764).

As to claim 11, Goldhaber teaches a catheter comprising a longitudinal catheter shaft (see Fig. 2 above) for positioning an ablation electrode within a patient's body (col.

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3, lines 32-41). An ablation electrode 14 is disposed on the shaft and the electrode has a continuous outer ablating surface area on the operative tip 16 (a part of the ablation electrode). The outer ablating surface area is adjustable since the operative tip portion of the ablation electrode is adjustable (col. 3, lines 1-8). Goldhaber does not expressly teach that the electrode is substantially comprised of metal. However, Eggers teaches ablation electrodes that are made of metal alloys (col. 22, lines 49-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement electrodes substantially comprised of metal since suitable metallic materials for an ablation electrode is recognized in the art, as exemplified by the teachings of Eggers (col. 22, lines 49-53).

As to claim 12, Goldhaber does not expressly teach that the electrode is substantially comprised of at least one of platinum, silver, gold, chromium, aluminum and tungsten. However, Eggers teaches that electrodes for ablation comprise electrically conducting materials such as alloys containing one or more of platinum, chromium, aluminum or tungsten (col. 22, lines 49-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the electrode of Goldhaber such that it substantially comprised at least one of platinum, silver, gold, chromium, aluminum or tungsten since suitable metallic materials for an ablation electrode is recognized in the art, as exemplified by the teachings of Eggers (col. 22, lines 49-53).

As to claim 13, Goldhaber does not expressly teach that the electrode is substantially comprised of a combination of at least two of: platinum; silver; gold;

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chromium; aluminum and tungsten. However, Eggers teaches that electrodes for ablation comprise electrically conducting materials such as alloys containing one or more of platinum, chromium, aluminum or tungsten (col. 22, lines 49-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the electrode of Goldhaber such that it substantially comprised a combination of at least two of platinum, silver, gold, chromium, aluminum or tungsten since suitable metallic combinations for an ablation electrode is recognized in the art, as exemplified by the teachings of Eggers (col. 22, lines 49-53).

9. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldhaber (U.S. Patent No. 5,234,429), as applied to claim 18 above, in view of Watson (U.S. Patent No. 5,788,715).

As to claim 19, Goldhaber teaches that the instrument is pulled out from the retract configuration to the extended configuration, but does not specifically disclose the actuation mechanism employed. Goldhaber does not expressly teach a pull wire configured to move the second electrode portion. However, Watson teaches that successive cylinders are arranged so that they telescope sequentially with successive applications of pulling forces on a pull wire (col. 4, lines 42-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement a pull wire connected to the second electrode portion because Watson teaches that successive cylinders are arranged so that they telescope sequentially with successive applications of pulling forces on a pull wire (col. 4, lines 42-50), and the connection the

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second electrode portion would give the user the ability to control the extension/retraction of the second electrode.

10. **Claims 12-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini (WO 95/20360), in view of Eggers (U.S. Patent 5,810,764).

As to claim 12, Silvestrini does not expressly teach that the electrode is substantially comprised of at least one of platinum, silver, gold, chromium, aluminum and tungsten. However, Eggers teaches that electrodes for ablation comprise electrically conducting materials such as alloys containing one or more of platinum, chromium, aluminum or tungsten (col. 22, lines 49-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the electrode of Silvestrini such that it substantially comprised of at least one of platinum, silver, gold, chromium, aluminum or tungsten since suitable metallic materials for an ablation electrode is recognized in the art, as exemplified by the teachings of Eggers (col. 22, lines 49-53).

As to claim 13, Silvestrini does not expressly teach that the electrode is substantially comprised of a combination of at least two of: platinum; silver; gold; chromium; aluminum and tungsten. However, Eggers teaches that electrodes for ablation comprise electrically conducting materials such as alloys containing one or more of platinum, chromium, aluminum or tungsten (col. 22, lines 49-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the electrode of Silvestrini such that it substantially comprised of a combination of at

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least two of platinum, silver, gold, chromium, aluminum or tungsten since suitable metallic combinations for an ablation electrode is recognized in the art, as exemplified by the teachings of Eggers (col. 22, lines 49-53).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN LEE whose telephone number is (571)270-1407. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. L./

7/2/09

Examiner, Art Unit 4137

/Gary Jackson/

Supervisory Patent Examiner

Art Unit 4137